

REMARKS

The application is amended and is believed to have been placed in condition for allowance.

Claims 1, 3, 4, 7, 8, 10, 11, 13 and 23-33 remain in the application.

Claims 10, 11, 18, 29 and 31-33 are withdrawn.

Amendments to the Disclosure

Independent claims 1, 7, 23, and 30 are amended to overcome the Official Action's formal rejections under Section 112 (further detailed below).

Claims 32-33 are canceled, without prejudice.

New claim 34 depends from claim 23, and finds support in the specification and the claims as originally filed.

Dependent claim 26 is amended to depend from claim 24.

The foregoing amendments to the claims find support in the specification and drawing figures as originally filed and do not introduce new matter.

For example, the amendments find support in the specification at page 5, line 18 to page 6, line 14; page 12, line 3-19; page 13, lines 21-30; page 20, lines 1-17; page 22, line 24 to page 23, line 3; original claim 1.

Formal Matters - Section 112

The Official Action rejected claims 1, 3, 4, 7, 8, 13, 23-28 and 30 under 35 USC 112, first paragraph as failing to comply with the written description requirement. The Official

Action states that the recitation "the gel framework configured" as recited in the aforementioned claims does not appear to be disclosed in the originally filed claims or specification.

The Official Action rejected claims 1, 3, 4, 7, 8, 13, 23-28 and 30 under 35 USC 112, second paragraph as being indefinite. In particular, the Official Action objected to the term "configured", stating that the term applies to a configuration of mechanical parts in a device, and has no meaning in the context of a claim drawn to a composition without parts to be arranged.

In response, it is respectfully submitted that independent claims 1, 7, 23, and 30 are amended as indicated above and are believed to overcome the Official Action's rejection.

In particular, each of the independent claims recites a gelling agent having a concentration such that a gel framework of the gelling agent breaks apart and releases the active ingredient upon forcible disruption by a person.

The recitation is definite, and finds support in the specification and the claims as originally filed as indicated above. For example:

...the at least one gelling agent providing, on solidification, a semi-solid gel having a gel framework comprising sufficient containment means for the at least one active ingredient during a period of storage; the gel framework being capable of breaking apart when the composition is forcibly disrupted by a

person and making the at least one active ingredient available for use in a personal care procedure.

In a first related aspect the at least one gelling agent is present at a concentration at least high enough to cause the composition to remain in a semi-solid state when held at a storage temperature such as below about 30 degrees Celsius, the concentration at the same time being sufficiently low to permit the semi-solid composition to break apart and render the at least one active ingredient available when disrupted by the person.

Page 5 line 18 to page 6 line 2.

It is therefore respectfully submitted that the independent claims 1, 23, and 30 have been placed into condition to overcome the rejections under Section 112 for new matter and indefiniteness.

Withdrawal of the rejections under Section 112, first and second paragraphs, is thereby respectfully solicited.

Claim Rejections - Obviousness-type Double Patenting

The Official Action provisionally rejected claims 1, 3, 4, 7, 8, 13, 23-28 and 30 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 17 of co-pending Application No. 12/067817.

In response, the provisional rejection is noted. However, since this rejection has been indicated as provisional, Applicant respectfully submits that no Terminal Disclaimer is required at this time. Should co-pending U.S. Application 12/067,817 go to allowance, for example, the matter of the provisional rejection with respect to the present application should be re-visited and a determination made at that time in

consideration of any amendments made to the claims of the present and the co-pending applications.

Claim Rejections - Section 103

The Official Action rejects claims 1, 3, 4, 7, 8, 13, 23-28 and 30 under 35 USC 103(a) as being unpatentable over Schmidt (U.S. Patent 5,354,551; hereinafter "SCHMIDT") in view of Alexander (WO 2002/026078, English Equivalent U.S. Publication 2004/0091431; hereinafter "ALEXANDER") and Grossmith (GB 750,126; hereinafter "GROSSMITH").

In response, it is respectfully submitted that none of the cited references as applied by the Official Action, individually or in combination, teaches or suggests a semi-solid composition as recited in independent claims 1, 23 and 30 wherein a gelling agent having a concentration such that a gel framework of the gelling agent breaks apart and releases the active ingredient upon forcible disruption by a person.

On the contrary, SCHMIDT teaches a thin film, not a compact bead as required by the present invention, and ALEXANDER fails to teach a homogenous and non-encapsulated single-dose gel bead comprised of a single dose of an active ingredient intimately mixed with a gelling agent wherein the gelling agent provides a gel framework.

The Official Action proposes that one of skill would have modified SCHMIDT to form the thin film into bead shapes and added colors to the compositions of SCHMIDT in order to make the

composition more attractive to children and to promote dental hygiene to children, as disclosed by the secondary reference.

The Official Action's rejections under Section 103 are respectfully traversed for at least the reasons set forth in the Declarations under Rule 132 provided by Mr. Carl Ernest Alexander and Mr. Patrick Joseph Silcock, respectively, as provided in the Appendix to this paper, and further for the reasons set forth below.

None of the cited references, individually or in combination, teach or suggest an active ingredient intimately mixed with a gelling agent with a concentration such that a gel framework of the gelling agent breaks apart and releases the active ingredient upon forcible disruption by a person, such as in a oral or dental procedure.

On the contrary, SCHMIDT teaches a water-soluble or water-swellaable film-forming agent that is dissolved or dispersed in the mouth to distribute its substances (column 1, lines 60-65; column 2, lines 40-42). SCHMIDT makes no teaching or suggestion of a breaking, or any quality of its thin film suggesting an ability or a tendency to break apart in response to forcible disruption such as in a oral or dental procedure. SCHMIDT unequivocally teaches dissolution as a result of interaction with moisture, e.g., on the bristles of a toothbrush or via saliva in the mouth, so that the strip is pre-dissolved and dissolved so

that the active ingredients develop full activity (column 3, lines 2-13).

Even if one of skill had motivation to modify SHMIDT to have a bead shape as taught by ALEXANDER, the result would fail to produce the composition that breaks apart as recited by the amended claims.

Further, the Official Action concedes that neither of SCHMIDT and ALEXANDER, individually or in combination, teach or suggest a gelling agent comprising agar or carrageenan, as recited by claims 1, 24-25, 30 and 31.

The Official Action further contends that one of skill would have been motivated by GROSSMITH to use either of agar and carrageenan as the gel forming agent in the compositions of the combined teachings of SCHMIDT and ALEXANDER in order to make single dose gel beads having good strength with good suspending power and temperature stability and low solid content with strong structure.

In response, it is respectfully submitted that GROSSMITH makes no teaching or suggestion of a composition suitable for use as a single-dose, semi-solid bead.

On the contrary, GROSSMITH is unequivocally directed toward a composition of soft jellies and viscous solutions for use as hand jellies, stabilizers, detergent builders, vehicles for medicaments, etc. (page 1, lines 10-14). Of the uses and application disclosed in the list on page 3, lines 21-45, not one

suggests a semi-solid bead. All of them, instead, are soft, liquid-like compositions of various viscosities, e.g., hand jelly, tooth paste, shampoo, creams, pastes, suspension jellies for food, surgical lubricant, culture medium for bacteriology, lotions, and thickeners for ice-cream and jams (page 3, lines 21-45).

In particular, GROSSMITH teaches a desired jelly texture "for filling into tubes or pots," (page 2, lines 49-50). Compositions of both agar-agar (Examples I, II, and IV of pages 2 and 3) and carrageenan (Example III of page 2) are unequivocally directed toward a "jelly of somewhat short texture" (page 2, lines 65).

In stark contrast, the present invention recites a "semi-solid composition". The specification as originally filed discloses semi-solid as "easily deformed by an applied force, yet retains a predetermined shape on removal of the force unless deformation exceeds a limit... [t]he force of gravity is less than the limit," (page 5, lines 8-11). The specification further describes the semi-solid composition as "being capable of breaking apart when the composition is forcibly disrupted by a person," (page 5, lines 24-25). None of the compositions taught by GROSSMITH even remotely suggest this feature.

On the contrary, GROSSMITH expressly teaches away from any composition of agar-agar with solid or semi-solid properties. "Agar-agar itself forms a jelly of somewhat short texture which,

when used as a hand jelly, breaks up into fragments which cannot be rubbed satisfactorily into the hands," (page 1, lines 39-43). "When it is employed in an aqueous solution at a high concentration, a jelly which does not liquefy up to about 85 C may be obtained, but such a jelly is so tough at ordinary temperatures that it cannot be readily squeezed from tubes," (page 1, lines 49-55).

Hence, GROSSMITH is not only explicit in its teaching toward a semi-liquid, jelly form contrary to the instant invention, but also expressly teaches against a composition of agar in any kind of solid form, a solid or semi-solid composition that breaks apart being unsatisfactory to GROSSMITH's intended purpose.

Obviousness does not exist where a combination of references would render the prior art unsatisfactory for its intended purpose (see MPEP § 2143.01). Therefore, the proposed combination of SCHMIDT and ALEXANDER with GROSSMITH fails to render as obvious the invention recited in the amended claims. The combination as proposed by the Official Action would yield a semi-liquid (that is, not semi-solid) jelly, formed into a bead-shape, which would be rendered into liquid form as a result of exposure to heat (syneresis) and mixture with water (see page 1, e.g., lines 46-47 and 65-69).

Therefore, it is respectfully submitted that the applied references fail to teach all the features recited in the independent claims as amended.

It is further respectfully submitted that no motivation existed for one of skill at the time of invention to have modified SCHMIDT as proposed, at least because the thin film of SCHMIDT invention would fail to function satisfactorily if formed into a bead shape, either spherical or semi-spherical.

The conclusion of obviousness is not sufficient merely because the references relied upon teach substantially all aspects of the claimed invention were individually known in the art; an objective reason to combine the teachings of the references. MPEP § 2143.01, paragraph IV. "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR v Teleflex*, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984; emphasis added).

Here, the Official Action proposes re-forming the SCHMIDT composition from a thin film into a spherical or semi-

spherical bead. It is respectfully submitted that SCHMIDT's composition as provided for dissolving from exposure to moisture would be rendered unsatisfactory if formed into a bead.

SCHMIDT teaches saliva and the intensive movement of the toothbrush the strip is pre-dissolved and dissolved so that the components can develop their full activity (column 3, lines 8-10). A bead shape will substantially interfere with this feature because a bead shape so significantly reduces the amount of surface area compared to a thin foil having the same volume.

Moreover, in experiments performed by Mr. Silcock, no benefit was drawn from forming SCHMIDT into the form of a bead (see Declaration of Patrick Joseph Silcock, page 8, lines 10-12). Indeed, according to the Rule 132 Declaration by Mr. Silcock as provided in the Appendix to this paper, one of skill would have found no teaching toward a satisfactory result by either of SCHMIDT or any combination of SCHMIDT with ALEXANDER.

SCHMIDT is further detrimental to ALEXANDER in that its property of being rapidly dissolved by moisture-exposure leads to stickiness and microbial spoilage while in storage. ALEXANDER overcomes mitigates these issues with its semi-solid outer shell. The combination as proposed to replace the composition of ALEXANDER with the composition of SCHMIDT formed as a bead would eliminate the advantages of ALEXANDER's shell and re-introduce the problems of poor shelf-life due to unintentional moisture exposure and spoilage through bacterial contamination.

The Official Action further proposes modifying the composition of SCHMIDT and ALEXANDER with GROSSMITH.

However, as indicated above, GROSSMITH expressly teaches against a composition of agar in any kind of solid form, a solid or semi-solid composition that breaks apart being unsatisfactory to GROSSMITH's intended purpose.

GROSSMITH instead is directed to semi-liquid forms. It is respectfully submitted that the jellies taught by GROSSMITH in the form of creams, pastes, etc. render SCHMIDT unsatisfactory for its intended purpose. For example, SCHMIDT teaches to "completely use the preparation without remains stating in the package" (column 1, lines 55-56). "A dosage is separated or peeled off... [to be] placed onto the moistened toothbrush or between the bristles," (column 3, lines 2-5). The foils are "printed, stamped, or punched in various manners," and "[p]ackaging is possible on non-polluting cardboard cases without the use of metals or plastics," (column 3, lines 21-23).

"[F]or cleaning and care of artificial teeth and dentures... a multiple coating is particularly advantageous, which comprises the cleaning, disinfecting and acidic components in one layer, while, optionally separated by an also water-soluble barrier layer, the second layer comprises the CO₂ or O₂ releasing substances," (column 3, lines 28-34).

How will a semi-liquid composition as taught by GROSSMITH achieve any of this?

Based at least on the above, it is respectfully submitted that the use of the compositions taught by GROSSMITH would render SCHMIDT and ALEXANDER unsatisfactory for its intended purpose. It is therefore respectfully submitted that no motivation exists to have made the modification proposed by the Official Action.

For all the foregoing, and further for the reasons set forth in the Declarations under Rule 132 provided in the Appendix to this paper, it is respectfully submitted that the claimed invention is novel and non-obvious over SCHMIDT, ALEXANDER and GROSSMITH.

Reconsideration and withdrawal of the rejections under Section 103 are respectfully requested.

Rejoinder of the Withdrawn Claims

It is respectfully submitted that withdrawn claims 10, 11, and 18 each properly depend from an allowable parent claim, requiring all the recitations of the allowable parent claim. It is further respectfully submitted that withdrawn claim 31, directed to a process for making the invention as recited in claim 1, is commensurate in scope with an allowable product claim and requires all the recitations of the allowable product claim.

Accordingly, rejoinder of all the withdrawn claims is respectfully requested.

Conclusion

From the foregoing, it will be apparent that Applicants have fully responded to the October 2, 2009 Official Action and that the claims as presented are patentable. In view of this, Applicants respectfully request reconsideration of the claims, as presented, and their early passage to issue.

In order to expedite the prosecution of this case, it is requested that the Examiner telephone the attorney for Applicants at the number set forth below if the Examiner is of the opinion that further discussion of this case would be helpful.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/Jeremy G. Mereness/
Jeremy G. Mereness, Reg. No. 63,422
209 Madison Street
Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

JGM/lrs

APPENDIX:

The Appendix includes the following item(s):

- ☒ - a 37 CFR 1.132 Declaration by Mr. Carl Ernest Alexander
- ☒ - a 37 CFR 1.132 Declaration by Mr. Patrick Joseph Silcock